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January 27, 2020

VIA ECF

The Honorable Robert Kugler
Senior United States District Court Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Courtroom 4D
Camden, NJ 08101

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Courtroom 3C
Camden, NJ 08101

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Kugler and Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Case Management Conference with the Court on January 28.

1. Expansion of the MDL & MDL Management

As the Court heard on January 15, 2020, and as set forth in Defendants' submission to the Court dated January 14, 2020, the inclusion of Irbesartan and Losartan raises issues pertaining to the management of the MDL. *See* Draft Tr. of 1/15/20 Status Conference, 14:2-19:10, attached as Exhibit A; *see also* Dkt. 338 at 1–7. Differences in the three drugs, such as, (i) their respective manufacturing processes; (ii) the alleged nitrosamine impurities, *e.g.*, NDMA, NDEA or NMBA,

and impurity levels affecting each drug; (iii) the scope of the separate recalls as to each drug, and (iv) the different supply chain participants involved with each drug, among other things, make the inclusion of Irbesartan and Losartan in the MDL more challenging than simply amending the Valsartan-only form documents and discovery requests that were approved by the Court in 2019. Indeed, some of the Defendants who manufacture, distribute, or sell Valsartan have not recalled, or do not manufacture, distribute, or sell, the other drugs. Moreover, Plaintiffs acknowledge that they are still evaluating *inter alia* (a) whether and how to amend the Valsartan-only Master Complaints to include the new drugs, (b) Plaintiffs' leadership in light of the new drugs; and (c) the amendment of the Court-approved Valsartan-only discovery to include Irbesartan and Losartan. *See* Ex. A, 1/15/20 Tr. at 14:2-16:9. Given these complexities, as discussed further below, Defendants suggest the parties and the Court determine whether the ordering of the claims as between the economic loss claims, including the work-up of class certification, and the personal injury cases should be determined.

While the parties generally agree that claims arising out of alleged impurities in Valsartan should proceed ahead of claims arising out of alleged impurities in Irbesartan and Losartan, the ordering of the Valsartan-only economic loss class action claims and the Valsartan-only personal injury claims could have a significant impact on the timing and scope of proceedings pertaining to Irbesartan and Losartan. Discovery relating to Valsartan manufacturing, testing, quality control, quality assurance, and regulatory filings and communications, among other Valsartan issues, should streamline similar discovery as to Irbesartan and Losartan, and judicial determinations as to whether the alleged nitrosamine impurities in Valsartan resulted in defective products, or were capable of causing the alleged physical injuries, should narrow the legal issues for Irbesartan and

Losartan proceedings. Conversely, class certification proceedings as to Valsartan, which, as discussed below, impose significant discovery obligations on both sides, would likely have limited impact, if any, on class certification proceedings as to Irbesartan and Losartan.

In Defendants' view, an efficient way to manage this MDL would be to stage the proceedings such that the legal question whether the alleged nitrosamine impurities in Valsartan resulted in defective products was resolved before the parties wade into the numerous complex issues pertaining to class certification as to the Valsartan economic loss claims, and before discovery pertaining to Irbesartan and Losartan manufacturing, distribution, and sales is required. Plaintiffs have refused to discuss managing the MDL in this way.

Prior to the expansion of the MDL, the Court made comments suggesting the economic loss class actions might proceed ahead of the personal injury claims. Accordingly, as set forth below, Defendants have attempted to discuss with Plaintiffs the class certification-related discovery they are required to provide. Plaintiffs did not express a preference to prioritize one type of Valsartan-only claim over the other, and refused to discuss their class certification discovery obligations.

As discussed below, Defendants request that the Court direct the parties to engage in further discussions regarding MDL management, with the objective of determining the ordering of cases as between the economic loss claims and the personal injury claims.

(a) <u>Irbesartan and Losartan Pleading and Discovery Issues</u>

During the CMC on January 15, 2020, the Court directed the parties to meet and confer on MDL management issues, as they had planned to do, with the explicit guidance that the parties should focus on the pleading issues relating to Irbesartan and Losartan. *See* Ex. A, 1/15/20 Tr. at

18:21-19:9. As the Court expressed, until those pleading issues are resolved, discovery relating to Irbesartan and Losartan should be "put on the back burner for now." *See id.* On January 22, 2020, Plaintiffs' Executive Committee and Defendants' Executive Committee, as well as counsel for one of the wholesalers, McKesson, and counsel for one of the retailers, Albertson's, convened a teleconference for the purpose of discussing MDL management and discovery issues.

The parties generally agree that the MDL proceedings relating to Valsartan should proceed on a different track than the MDL proceedings relating to Irbesartan and Losartan. However, they did not resolve any Irbesartan and Losartan pleading issues because, as Plaintiffs explained during the meeting, they were still in the process of determining, among other things: (1) how many personal injury cases relating to each drug might be filed; (2) which law firms have filed or may file Irbesartan and Losartan claims; (3) whether and how Plaintiffs' leadership structure will need to be modified; and (4) the identity of class representatives for the consumer, third-party payor (TPP), and medical monitoring class actions arising out of the alleged impurities in Irbesartan and Losartan. Plaintiffs were unwilling to commit to or provide an estimate of a date by which the Irbesartan and Losartan Master Complaints will be filed.

Given the Court's comments about resolving the Irbesartan and Losartan pleading issues first, and in light of Plaintiffs' ongoing evaluation of those issues, the parties seemed to agree that discussing Irbesartan and Losartan discovery was still premature.

(b) MDL Management in Light of the Expansion

Although Plaintiffs declined to discuss the ordering of Valsartan-only claims, including the scheduling for the work-up of class certification, Defendants view this issue to be paramount to the management of the MDL, especially in light of its recent expansion. This is particularly true

given the ***dozens*** of Defendants and various supply-chain tiers involved in the separate claims relating to each of the three drugs, and the impact that these complex case management issues are already having on the parties' attempts to meet and confer on matters as basic as the scope of the DFS and Rule 34 discovery. *See infra* 19–26 (discussing status of downstream defendant discovery and manufacturer DFS).[1] Indeed, unlike in *Benicar*, where there was only one drug, only personal injury claims, i.e., failure to warn, and only two defendants (which were jointly involved in the manufacture and sale of the drugs at issue), the class certification proceedings required in connection with Plaintiffs' economic loss class action claims in this MDL, which are asserted on behalf of consumers and separately on behalf of TPPs, require dozens of parties to undertake significant fact and expert discovery related to the procedural thresholds under Rule 23.

Moreover, the class representatives would be required to meet significant burdens of production, including the following categories of information, as well depositions of the consumer and TPP class representatives, and class certification expert designation and depositions:

- insurance policies and ERISA benefit plan agreements (the "Plans");
- multiple insurance products ("Products") providing drug coverage under each Plan;
- Formularies/Preferred Drug Lists which list all drugs covered and provide the relevant reimbursement scheme for the level at which the drug is classified in each Product—both for VCDs and all potential alternate hypertension drugs ("Alternate Meds") that would have been prescribed to Members if a VCD were not;
- the amounts the putative class members would have paid for Alternate Meds because, if they cost the same or more than the VCDs, the class was not injured;

[1] The identity of the supply chain participants that may be named as Defendants in a Master Complaint for Irbesartan or a Master Complaint for Losartan is not known, and there are differences among the supply chain participants as to each drug and their involvement with the allegations at issue.

- TPP Pharmacy & Therapeutics Committee ("P&T) minutes and Quality Assurance Programs reflecting safety assessments of the VCDs and Alternate Meds;
- TPP and/or Pharmacy Benefit Manager ("PBM") Help Desk notes reflecting Member and physician complaints and/or concerns regarding VCDs;
- full Plan Member medical records to reflect individual VCD efficacy, side effects and possible Alternate Meds; and
- spreadsheets reflecting the gross prices/copays paid, discounts, fees and net payments/copays paid for VCDs and Alternate Meds.[2]

In light of the breadth and complexity of these issues, determinations as to the ordering of the economic loss class certification cases and personal injury cases should enhance the management of the MDL. Were the Court or the parties to decide that specific issues/claims were preferable vehicles to advance the matters before the Court—for example, carving out an issue for early work-up and trial such as defectiveness with respect to Valsartan only, which could have implications for Irbesartan and Losartan—the parties could focus on the parties and discovery necessary to resolve those issues and/or claims.

Accordingly, Defendants request that the Court direct the parties to engage in such discussions, with the objective of determining the ordering of the claims as between the economic loss claims and the personal injury claims.

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[2] These documents are anticipated by the Economic Loss PFS, and, to the extent Plaintiffs take the position they are not, Defendants anticipate Rule 34 discovery on such foundational class issues. Given that MSP, one of only two TPP class representatives, is not, in fact, a TPP, but merely an alleged assignee of claims from certain identified and unidentified TPPs, presumably without easy access to the above documents, Defendants would like to discuss with Plaintiffs the best mechanisms for procurement of this information for the "MSP-represented" portion of the class. Defendants also would require prompt discovery relating to MSP's alleged assignments.

2. Direct Filing Order

Defendants appreciate the opportunity to discuss with the Court certain defendants' (the "Objecting Defendants")[3] objections to the direct filing of complaints against them in this multidistrict litigation. Through this pre-hearing submission, Defendants hope both to explain the Objecting Defendants' rationales for so objecting and provide the Court with potential mechanisms it might consider to move the litigation forward in light of the Objecting Defendants' objections.

At their core, Objecting Defendants' objections are based in the preservation of foundational Due Process rights relating to litigation, and the correlated defenses, arguments and objections that defendants use to assert them. It bears strong emphasis at the outset that the Objecting Defendants have no intention or desire whatsoever to unduly disrupt or delay the orderly continuation and maintenance of this complex multi-party MDL. To the contrary, Objecting Defendants are cognizant and quite mindful of the Court's likely desire to avoid any such disruption, and they have endeavored to provide the Court with suggestions of reasonable pathways forward.

This submission has three parts. *First*, Objecting Defendants outline the relevant procedural history relating to the direct filing issue, which they believe important to the Court's consideration of these issues. *Second*, Objecting Defendants provide a brief summary of their objections and rationales for objecting. *Third*, Objecting Defendants provide the Court with a

[3] The Objecting Defendants are the following: Albertsons, Amerisource Bergen, Cardinal Health, Inc., CVS, Express Scripts Inc., Express Scripts Holding Co., Humana Inc., Humana Pharmacey, Inc., Legacy, and McKesson.

proposed Superseding Direct Filing Order[4] they believe the Court would be empowered to enter, that would implement the existing direct filing protocol as to the parties stipulating to direct filing. Recognizing that the Court may ultimately determine that, notwithstanding their objections as to the Court's authority to do so, it may and should enter an order authorizing direct filing against the Objecting Defendants over their objections while at the same time preserving the Objecting Defendants' rights, Objecting Defendants also provide the court with the type of alternate draft order[5] that the Court might wish to consider as it makes those determinations.

Under either scenario, Defendants respectfully request that the Court grant each of them prompt leave to file motions to dismiss under Federal Rules of Civil Procedure 12(b)(2)-(5)[6] on grounds of lack of personal jurisdiction, improper venue, and/or insufficient process or service of process and set a reasonable briefing schedule on those issues given the large number and diverse set of defendants, claims and issues in this litigation.

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[4] As discussed previously with the Court, Defendants provided Plaintiffs with their proposed Superseding Direct Filing Order on Friday, January 24, 2020. Objecting Defendants offered to make themselves available to meet and confer with Plaintiffs over the weekend or Monday to discuss these issues. Plaintiffs and Defendants corresponded over the weekend and, per Plaintiffs' request, met and conferred by telephone on Monday, January 27. The substance of the parties meet and confer conversation is discussed more fully in the footnotes below.

[5] Plaintiffs and Objecting Defendants discussed this type of alternate order during their meet and confer telephone conference on Monday, January 27. As more fully discussed in footnote 9 below, in light of Plaintiffs' statements on the parties' teleconference that they are amenable to and would prefer this type of order which continues to fully preserve all Defendants' rights, defenses and arguments relating personal jurisdiction and venue in both this Court and any other court or jurisdiction while at the same time authorizing direct filing against defendants over the Objecting Defendants' objections, Objecting Defendants promptly provided Plaintiffs with a copy of the draft alternate order for their review.

[6] Defendants group these motions to dismiss mindful of Federal Rule of Civil Procedure 12's directive that they be brought together. Fed. R. Civ. P. 12(h)(1). The applicability of any particular type of motion or ground for dismissal may vary by individual Defendant.

(a) Procedural History Relating to Direct File Order

The Valsartan MDL was first created when, on February 14, 2019, the Judicial Panel on Multidistrict Litigation (JPML) issued a Transfer Order (JMPL Doc. 229; Doc. 1) transferring certain actions identified on Schedule A of that order and pending outside the District of New Jersey to this Court for coordinated pretrial proceedings, and creating MDL No. 2875 relating to claims based on usage or purchase of generic formulations of Valsartan allegedly containing NDMA or NDEA impurities.

Between the issuance of the first JPML Transfer Order and this Court's April 9, 2019 entry of Case Management Order No. 3 (Doc. 76) (CMO No. 3) governing the direct filing of certain actions into MDL No. 2875, the Clerk of the JPML finalized and transmitted to this Court three Conditional Transfer Orders (CTOs) initiating the transfer of approximately 26 tag-along actions identified in those CTOs. (Doc. 3, 22, 67) Numerous additional CTOs have since followed.

On April 2, 2019, this Court entered Case Management Order No. 2 (Doc. 72) staying Defendants' obligation to answer, move or otherwise respond to Plaintiffs' Complaints pending further Court order, and preserving all of Defendants' objections and affirmative defenses. The Court has subsequently reiterated and directed that, notwithstanding Defendants' requests to do so, Defendants may not file motions responding to Plaintiffs' Complaints absent Court order permitting them to do so. (Doc. 183)

On April 9, 2019, with the stipulation of Plaintiffs and those certain limited defendants who at that time had been served and properly joined in this litigation, this Court entered Case Management Order No. 3 (Doc. 76) (CMO No. 3) governing the direct filing of certain actions into MDL No. 2875.

On June 17, 2019, Plaintiffs in the Valsartan-related actions filed a Consolidated Amended Economic Class Action Complaint (Doc. 121), a Master Personal Injury Complaint (Doc. 122), and a Consolidated Medical Monitoring Class Action Complaint (Doc. 123) naming certain new and additional parties as Defendants in these various actions.

Subsequent to the entry of CMO No. 3 and Plaintiffs' filing of these new and amended complaints, Plaintiffs have attempted to serve and join many new and additional parties as defendants in these various actions.

On December 18, 2019, the JPML issued a Transfer Order (JMPL Doc. 401; Doc. 325) transferring the four (4) actions identified on Schedule A of that order and pending outside the District of New Jersey to this Court for coordinated pretrial proceedings, expanding MDL No. 2875 to include those claims relating to usage or purchase of generic formulations of Losartan and Irbesartan allegedly containing nitrosamine impurities, and renaming the MDL "*In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*."

On January 15, 2020, Judge Schneider held a telephonic status conference wherein Plaintiffs raised, and for the first time the parties briefly discussed as between themselves, Plaintiffs' request that a direct filing order be entered relating to newly arising cases and that such an order be entered quickly. During that telephone conference one of the counsel for Defendants stated that she would poll the various defendants to determine if there may be any objections and, assuming no objections, work to compile a draft direct filing order for Plaintiffs and Defendants to meet and confer upon.[7]

[7] During the January 15, 2020 telephone conference, Judge Schneider also addressed Legacy Pharmaceutical Packaging, LLC's ("Legacy") motion to dismiss for lack of personal jurisdiction

Upon subsequent discussion with the larger defense group, including new defendants who were not involved in the litigation when CMO No. 3 was negotiated, it was determined that Defendants did not have consent or consensus from all the current defendants as to the complex issues underlying direct filing. Defendants communicated to Plaintiffs the status of their inability to reach immediate consensus across the multitude of defendants in such a short period of time, and further offered to arrange a meet and confer with Plaintiffs to discuss the issues. Plaintiffs' counsel declined Defendants' offer to meet and confer, and, similarly, was not inclined to discuss the issue when the plaintiff and defense executive committees met and conferred by telephone on Wednesday, January 22. To the contrary, on that call Plaintiffs' counsel informed Defendants that he had initiated the filing of a letter with the Court on the issue, and Plaintiffs' letter requesting an immediate telephone conference was indeed filed during the parties' meet and confer telephone conference.

After Defendants responded to the letter by email explaining the procedural history outlined in the paragraph above, Judge Schneider responded by email and directed that the issue should be placed on the agenda for the upcoming in person case management conference on

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(Doc. 333). Judge Schneider referenced the preexisting Court-ordered stay of any motions practice relating to complaints and indicated that it would likewise apply to Legacy, but nonetheless permitted Legacy to file a letter request to the Court to ask for leave to so move. The Court further indicated that if other Defendants wished to be heard on the question of leave to file similar motions they may so indicate.

Through this pre-hearing submission, all Defendants wish to so request leave to file motions to dismiss under Federal Rules of Civil Procedure 12(b)(2)-(5) on (as applicable) grounds of lack of personal jurisdiction, improper venue, and/or insufficient process or service of process and set a reasonable briefing schedule on those issues given the large number and diverse set of defendants, claims and issues in this litigation.

Tuesday, January 28. Judge Schneider further directed that parties that object to the entry of a direct filing order appear in person at the January 28 case management conference to explain why they object to the entry of a direct filing order.

(b) Objecting Defendants' Objections to Direct Filing

The Objecting Defendants object to the entry of a direct filing order governing any complaints or claims against them because each Objecting Defendant wishes to expressly preserve and promptly assert its defenses relating to this Court's exercise of jurisdiction over them—and the various claims asserted against them—in this multi-district litigation as to all matters both pretrial and trial.[8]

Absent express consent and stipulation, no statute or rule authorizes direct filing of complaints in a forum where the requisite bases for jurisdiction and venue are absent. Numerous courts to have considered the issue have concluded precisely that, dismissing directly filed actions where Defendants did not so stipulate. *See In re Takata Airbag Prods. Liab. Litig.*, 379 F. Supp. 3d 1333, 1338, 1344 (S.D. Fla. 2019) (dismissing directly filed actions where, *inter alia*,

[8] During the parties' rather extensive and productive meet and confer telephone conference on Monday, January 27, Plaintiffs expressly reiterated and confirmed more than once their position that neither the existing CMO No. 3 nor any proposed or alternate superseding direct filing order alters any substantive rights of any Defendant, specifically including Due Process rights relating to personal jurisdiction and venue, and that all Defendants have preserved and should continue to preserve all rights, defenses and arguments relating to personal jurisdiction and venue in this Court or in any other court without exception. Plaintiffs agreed that there should not be "one inch of doubt" now or in the future that all Defendants have so preserved all their rights, defenses, and arguments on these issues and any others.

Defendants, both objecting and not, appreciate Plaintiffs' forthcoming and direct agreement and insistence on each of these points. For the reasons set forth herein, however, Objecting Defendants nonetheless believe they should object to direct filing and would propose an order along the lines of Attachment A.

"Defendants did not stipulate to waiving personal jurisdiction"); *In re NHL Players' Concussion Litig.*, 2019 U.S. Dist. LEXIS 175978, at *13–15 (D. Minn. Oct. 10, 2019) (dismissing directly filed action where defendant did not stipulate to personal jurisdiction and plaintiff did "not plead any injury in [forum] resulting from the NHL's acts or omissions . . ."); *see also Fin. Inst. Track Litig. v. Heartland Bank*, 2011 U.S. Dist. LEXIS 34953, at *20, 33, 88 (S.D. Tex. Mar. 31, 2011) (recognizing that direct filing "present[s] jurisdictional, venue, and related issues . . ." and dismissing directly filed actions in MDL when defendants did not expressly waive 12(b)(2) defenses).

Objecting Defendants respectfully submit that there are foundational jurisdictional defects present in all or many of the cases and claims asserted against each of them—direct filed or otherwise. *See, e.g.*, *Bristol-Myers Squibb Co. v. Super. Ct. of Cal.*, 137 S. Ct. 1773, 1780-81 (2017) ("When there is no . . . connection [between the forum and the specific claims at issue], specific jurisdiction is lacking regardless of the extent of a defendant's unconnected activities in the State."); *Horowitz v. AT&T, Inc.*, 2018 U.S. Dist. LEXIS 69191, at *47 (D.N.J. Apr. 25, 2018) (Martinotti, J.) (holding "there must be a connection between [each plaintiff's] claims and [each Defendant's] activities within New Jersey, even if [certain plaintiffs'] claims are similar or identical to claims brought by the resident named plaintiffs."); *Chernus v. Logitech, Inc.*, 2018 U.S. Dist. LEXIS 70784, at *14-18 (D.N.J. Apr. 27, 2018) (Wolfson, J.).

Mindful of the Court's repeated and express orders and directives (*see* Doc. 72; Doc. 183), reiterated as recently as the January 15, 2020 telephone status conference, that Defendants shall not file motions or briefing relating to any grounds for dismissal, Objecting Defendants (and indeed all Defendants) believe and respectfully submit these issues should be briefed and decided

promptly. *In re Lipitor Antitrust Litig.*, 722 F. App'x 132, 137–38 (3d Cir. 2018) (concluding "personal jurisdiction motion . . . should have logically preceded any decision under Rule 12(b)(6)") (citing *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 430-31 (2007) ("'Without jurisdiction the court cannot proceed at all in any cause'" (quoting *Steel Co. v. Citizens for Better Environment*, 523 U.S. 83, 94 (1998))); *see also Steel Co.*, 523 U.S. at 94 ("Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.") (citation omitted).

It is particularly useful that these issues are arising in the context of this Court's present evaluation of MDL case management. Beyond consistency with "the bounds of authorized judicial action and . . . fundamental principles of separation of powers," *Steel Co.*, 523 U.S. at 94, deciding these threshold jurisdictional issues now will only aid in the streamlining of this multi-faceted and numerous-party litigation. In short the dismissal of improper parties and claims at the outset can only serve to make whatever case(s) remain more compact, efficient and manageable. And the jurisdictional issues will only get more complex for the Court to decide as new parties are added to the expanded MDL as Plaintiffs suggest they may be.

For the reasons, the Objecting Defendants do not consent to direct filing and respectfully request a reasonably prompt opportunity to brief motions to dismiss relating to personal jurisdiction, venue and process. Objecting Defendants look forward to discussing these issues further with the Court on Tuesday.

(c) Proposed Superseding Direct File Order

Mindful of Plaintiffs' expressed urgency regarding the direct filing issue and the Court's directive that the issue should be discussed at the January 28 Case Management Conference,

Defendants conferred among themselves with an eye toward providing a specific proposal for plaintiffs and the Court to consider.

1. Order Proposed by Objecting Defendants

The resulting Objecting Defendants' proposed Superseding Direct Filing Order[9] is attached as **Exhibit B.** A comparison against CMO No. 3 is attached for the Court's convenience as **Exhibit C.**

As the Court will see, the proposed order amends the language of CMO No. 3 to account for the Objecting Defendants[10] that do not stipulate to direct filing, and applies the protocol across the expanded MDL. Objecting Defendants also added relevant procedural history and context at the beginning of the proposed order, to provide context for the Court and parties who may later join this litigation.

No Defendant objects to the entry of a Direct Filing Order in the form of the proposed Superseding Direct Filing Order. Certain defendants, to be identified in the proposed order as "Stipulating Defendants"[11] are those that would stipulate to the proposed Superseding Direct Filing Order. Certain other defendants wish to take no position on the proposed Superseding Direct

[9] During the parties' January 27 telephonic meet and confer, Plaintiffs expressed general comfort and agreement with the proposed order, excepting a review of the procedural history described therein and that Plaintiffs wish that direct filing be applied to the Objecting Defendants notwithstanding their objections.

[10] The Objecting Defendants are the same identified in footnote 4 above.

[11] The Stipulating Defendants are as follows: Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, the Teva Defendants (Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis Pharma, Inc., and Arrow Pharm (Malta) Ltd.), Hetero USA, Inc., the ZHP Defendants (Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Solco Healthcare U.S., LLC, and Prinston Pharmaceutical Inc.), and Mylan Pharmaceuticals Inc..

Filing Order but have indicated that they would stipulate to a direct filing order in the form of the attached if it were approved by the Court.[12]

2. *Alternate Draft Order Not Proposed or Consented but Presented for Discussion Purposes*

Recognizing that the Court may ultimately determine that, notwithstanding their objections as to the Court's authority to do so, it may wish to enter an order authorizing direct filing against the Objecting Defendants over their objections while at the same time preserving the Objecting Defendants' rights, Objecting Defendants thought it might assist the Court to see what that type of order might look like. The Alternate Order for discussion is attached as **Exhibit D**. A comparison against CMO No. 3 is attached for the Court's convenience as **Exhibit E.** To be clear, and for the avoidance of any doubt, Objecting Defendants do not believe this Court has authority to enter such an order under 28 U.S.C. § 1407 and would object to its entry. Should the Court disagree, however, this type of order might provide the Court a mechanism to move the MDL forward.

Under either scenario, and for the reasons described above Defendants respectfully request that the Court grant each of them prompt leave to file motions to dismiss under Federal Rules of Civil Procedure 12(b)(2)-(5) on grounds of lack of personal jurisdiction, improper venue, and/or insufficient process or service of process and set a reasonable briefing schedule on those issues given the large number and diverse set of defendants, claims and issues in this litigation.

[12] These "Take No Position" Defendants are as follows: AvKare, Camber, The Harvard Drug Group, LLC (d/b/a Major Pharmaceuticals), Kroger, Torrent, Walmart, NuCare Pharmaceuticals, Inc., Bryant Ranch Pre-Pack Pharmaceuticals, Pharma Pac, .

3. Legacy Pharmaceutical Motion to Dismiss

During the January 15, 2020 status teleconference, the Court stated that Legacy Pharmaceutical Packaging, LLC, could seek leave to re-file a motion to dismiss on personal jurisdiction grounds by filing a letter application in advance of the January 28 case management conference. That letter application is filed at Dkt. 350. Should the Court grant Legacy's application, Defendants with personal jurisdiction defenses reserve the right to join in such briefing, or to supplement it as necessary to raise those defenses.

4. Downstream Defendant Discovery

While the Court previously has communicated its goal to finalize Non-Manufacturing Defendant ("NMD") discovery at the January 28 conference, the Court surely anticipated that the discovery process would include adequate time for the NMDs to review proposed discovery, consult with their respective clients, meet and confer with Plaintiffs as to scope, prepare written objections, and brief any remaining issues in advance of this conference. However, as explained in detail below, Plaintiffs served their first attempt at tailored requests on NMDs after hours this last Friday, January 24, 2020, leaving the NMDs just one business day (today) to evaluate the requests, communicate with clients, prepare objections and brief the issues for the Court.[13] To

[13] On December 18, the Court struck Plaintiffs' proposed RFPs as not sufficiently tailored to the NMDs. Since that date, and as detailed herein, the NMDs worked quickly to collect information from their clients, and even prepared their own requests for production to facilitate the meet and confer process and for Plaintiffs' consideration in drafting. Unpersuaded, after hours on January 22, 2020, Plaintiffs served RFPs largely reminiscent of their stricken RFPs, now dividing them into "Phase 1" and "Phase 2" requests (a phasing process apparently created—but not explained—by Plaintiffs). Then, after hours on January 24, Plaintiffs served their RFPs with only the so-called "Phase 1" requests, for the first time giving NMDs something approaching the Court's order, but leaving only one business day for NMDs to do anything about it.

force the NMDs to go forward with a full hearing on these so-recently-received RFPs, and to have the Court rule on the complex issues involved that NMDs have not been able to discuss with their clients or brief for the Court, would greatly prejudice NMDs.

To be clear, the NMDs understand the Court's prior directives and that the Court has determined that discovery can be taken from the NMDs. The NMDs do not argue this point, and all have participated in this process in good faith in an attempt to present only the necessary disputes to the Court. However, the NMDs are not a monolith—they are individual entities with differing document protocols and procedures, and despite significant efforts by counsel for the NMDs to move this process along, Plaintiffs' delay in actually drafting a set of discovery to the NMDs on which to meet and confer has resulted in insufficient time for the NMDs to meet the Court's stated goals. Plaintiffs' counsel have refused to discuss an extension of time to meet and confer on these very important issues, instead communicating that they will push to finalize this discovery during the January 28 conference. Again, this is highly prejudicial to the NMDs.

The NMDs therefore request that this Court order further conference between the parties, and continue the discussion of NMD discovery until the February 26 conference—or until a date convenient to the Court—to allow the parties to be fully heard and for the Court to make informed rulings.

(a) Relevant Timeline

In October of 2019, this Court authorized Plaintiffs to seek discovery from NMDs in the form of a Defendant Fact Sheet ("DFS"). Following a November 6 discovery conference, the Court also permitted Plaintiffs to serve initial Rule 34 requests on the NMDs, which were to be served on or before November 26. *See* Dkt. No. 292.

On November 26, Plaintiffs served omnibus Rule 34 requests directed to all NMDs, which comprised 65 individual document requests, with 151 discrete subparts, on 15 separate topics, and not targeted to any specific level of the supply chain. Following initial meet and confer efforts regarding the impracticality and breadth of the requests, Plaintiffs served amended proposed requests on December 10, 2019. Thereafter, on December 18, the Court struck the amended RFPs, and in a telephone conference with the Court that same day, requested that Plaintiffs determine what information was required from the NMDs at this point in the litigation, and to serve a streamlined set of discovery on the individual tiers of defendants. During the December 18 conference, the parties agreed to meet and confer regarding their respective discovery capabilities in order to inform Plaintiffs' efforts to streamline, after which Plaintiffs would circulate new proposed RFPs. The meet and confer efforts of the various NMD levels are detailed below.

At the most recent discovery conference on January 15, the parties represented to the Court that they continued to work towards the January 28 deadline, and that they were hopeful that they could finalize discovery by that date. During that conference, Plaintiffs represented to the Court and counsel that they would send proposed discovery requests and DFS comments by the end of that week—or by January 17. Despite this representation, Plaintiffs failed to send proposed requests until the evening of January 22, with amended requests following on the evening of January 24.

1. Retailer/Pharmacy Defendants

Following the December 18 conference with the Court, the Retailer/Pharmacy Defendants quickly made efforts to consult with each other and their respective clients to determine their respective discovery capabilities—i.e. a determination of what information is kept in course of

pharmacy business and what information these defendants can provide to Plaintiffs up and down the supply chain. Despite the limitations imposed by the holidays, including corporate closures and limited availability of necessary personnel, the Retailer/Pharmacy Defendants worked quickly to compile necessary information, going so far as to prepare their own comprehensive set of Rule 34 requests to facilitate the meet and confer process.

On January 9, the Retailer/Pharmacy Defendants sent their proposed RFPs to Plaintiffs. *See* Exhibit F. Following a 90-minute meet and confer that day, Plaintiffs agreed to review the proposed RFPs among themselves and with their experts, and to circulate any additional requests upon further consideration.

During the telephonic discovery conference on January 15, the parties advised the Court that they were making progress and hoped to finalize the discovery by January 28. Counsel for the Retailer/Pharmacy Defendants advised the Court, however, that finalizing discovery hinged on receipt of Plaintiffs' proposed RFPs, which had not yet been served by Plaintiffs. During the January 15 conference, Plaintiffs represented that a proposal was forthcoming and would be received by the end of that week, or by January 17. It was not. Plaintiffs did not serve requests for production relating to the downstream defendants until late Wednesday night, January 22. *See* First Proposed RFPs to Retailer/Pharmacy Defendants, Exhibit G. Plaintiffs then insisted that the Retailer/Pharmacy Defendants be prepared to meet and confer on and finalize these requests by the end of the week—less than two days later.

The proposed RFPs included 95 separate requests, not including subparts, and were divided into two separate "phases," with the first phase contemplating response from these defendants on 49 separate requests on 12 distinct topics; the proposed requests disregarded the draft prepared by

the Retailer/Pharmacy Defendants, and in significant part repeated their original (stricken) requests. It was not initially clear if Plaintiffs only intended to seek approval to serve the "Phase One" requests by tomorrow's status conference. Regardless, even the "Phase One" requests are facially problematic and fail to adhere to the Court's directives to serve focused requests to each tier of NMDs.[14] And contrary to Plaintiffs' anticipated suggestion, the "Phase 1" requests are not narrow. Indeed, the requests functionally seek all information available about every single valsartan drug sold or purchased at any time—whether or not even subject to recall—including recipients, pricing, packaging, insurance information, and warranties. The "Phase 1" requests also insert new categories of information not previously discussed in meet and confers or even communicated to defendants in any respect in the weeks since that call.[15]

Upon receipt of the voluminous requests, counsel for the Retailer/Pharmacy Defendants reached out to Plaintiffs, advising that they were reviewing the requests, but obviously would need time to consult with their respective clients, and proposed a meet and confer the following week. Despite delays solely of their own making, Plaintiffs were insistent that discovery should be finalized by tomorrow's conference, and were unwilling to discuss any continuance.

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[14] To be fair, Plaintiffs included a footnote that "[e]ach request is to be interpreted consistent with the Court's" rulings and orders, including Dkt. 303. Instead of modifying the requests in accordance with the Court's rulings, however, Plaintiffs are asking each NMD to interpret the Court's prior rulings and eliminate or narrow the requests accordingly.

[15] For example, the new requests mention for the first time "EDI 867 Product Transfer and Resale Report data"—a term not introduced in any of the prior drafts. *See* Request No. 6 to Retailer/Pharmacy Defendants (Exhibit G).

Thereafter, after business hours on Friday, January 24, Plaintiffs served an amended set of RFPs on the Retailer/Pharmacy Defendants, this time with only the so-called "Phase 1" requests, noting that "[s]ome of the requests were by design over-inclusive to be further narrowed through discussion." January 24, 2020 Email from C. Whiteley to S. Johnston, attached as Exhibit H and Second Proposed RFPs, attached as Exhibit I. The second set of requests—received less than one business day ago—comprise 40 separate requests, excluding subparts, and by Plaintiffs' own admission, are meant to be a jumping-off point for further meet and confers.

2. Wholesaler Defendants

Similarly, after the Court struck Plaintiffs first set of Rule 34 Requests, the Wholesaler Defendants initiated the meet and confer process with Plaintiffs. The first meet and confer took place on December 24, at which point it was anticipated that Plaintiffs would provide a revised set of RFPs. A second meet and confer was scheduled for approximately three weeks later, January 14. By that date, however, Plaintiffs had not sent any revised RFPs. Accordingly, and following the second meet and confer conference, the Wholesaler Defendants prepared and sent to Plaintiffs a set of proposed RFPs. The parties then met and conferred for the third time on January 17. Plaintiffs provided no revisions or comments to the Wholesaler Defendants' proposed RFPs in advance of that third conference.

During the January 15 discovery conference, as they had done with the Retailer/Pharmacy Defendants, Plaintiffs communicated to the Court their intention to served proposed RFPs by January 17. As with the Retailer/Pharmacy Defendants, however, Plaintiffs failed to serve their first draft requests until the evening of Wednesday, January 22 (*see* First Proposed RFPs to Wholesalers, Exhibit J) but nevertheless requested to meet and confer by the end of the week. In

an apparent effort to meet the January 28 deadline, Plaintiffs likewise served the Wholesaler Defendants with amended proposed RFPs after hours on Friday, January 24. *See* Second Proposed RFPs to Wholesalers, Exhibit K. Those amended proposed RFPs only included the so-called "Phase 1" requests, noting that "[s]ome of the requests were by design over-inclusive to be further narrowed through discussion." January 24, 2020 Email from C. Whiteley to J. Geoppinger, attached as Exhibit L. The second set of requests—received less than one business day ago—comprise 36 separate requests.

(b) Scope of the Proposed DFSs

On November 1, the Retailer/Pharmacy Defendants provided comments and proposed redlines relating to the DFS. *See* Exhibit M. All other Defendants did the same on or about October 23, 2019. *See* Exhibit N. Plaintiffs provided no comment on these drafts at any time. Rather, instead of addressing the comments from NMDs or meeting and conferring with the downstream defendants about their comments, Plaintiffs simply served updated, *more expansive* proposed fact sheets to the Retailer/Pharmacy Defendants on January 21, and on the Wholesaler Defendants on January 23. The revised DFSs add new categories of information not previously identified to the NMDs defendants or on the initial proposed DFS. For example, the new DFS requests the wholesaler, finished dose manufacturer, and Affected API manufacturer for each "Affected Drug," as well as manufacturing and expiry information for each drug. None of that information was in the initial DFS draft.

(c) Additional Time is Warranted for the Parties to Agree to NMD Discovery and to Narrow NMD Discovery Issues to Be Decided by the Court

As of the writing of this submission, neither Plaintiffs nor the NMDs are in a position to finalize discovery as to the NMDs. While the NMDs anticipate that Plaintiffs will argue that they were prepared to finalize discovery late last week, the fact remains that Plaintiffs failed to even serve proposed requests until three days ago, with amended requests served just one day ago. The NMDs undertook significant efforts to prepare for meet and confers with Plaintiffs, going so far as to draft their own RFPs to facilitate the process. In turn, Plaintiffs (who notably do not have to seek client input on discovery matters) failed to act with the same urgency. While the NMDs remain committed to working cooperatively, given the timing of Plaintiffs' revised drafts, the delay has deprived the NMDs of the opportunity to consult with their respective clients, to substantively meet and confer with Plaintiffs before presenting these issues to the Court, to prepare targeted objections, and to present the remaining issues to the Court by tomorrow's conference. Accordingly, the NMDs request that this Court order further conference between the parties, and continue the discussion of NMD discovery until the February 26 conference—or until a date convenient to the Court.

5. Defendant Fact Sheets for Manufacturer Defendants

During the January 15, 2020 status teleconference, the Court stated that it is "clearly" and "unquestionably the case that if there is going to be a fact sheet for the defendants, it can't duplicate what's in the request for production." Ex. A, 1/15/20 Tr. at 26:18-21; *see also id.* at 27:18-20 ("[T]here can be no legitimate dispute that the fact sheets shouldn't duplicate what the … manufacturing defendants have to answer in the request for production…."). For that reason, the

Court directed the Plaintiffs to rework their draft Defendant Fact Sheets ("DFSs") directed toward the Manufacturer Defendants so that it is limited to information "that's not covered by the document requests." *Id.* at 27:23-24. The Court further instructed that it is likely "not wise to work from a draft from October, since so much work has been done since October that would moot out" the substance of the earlier draft DFS. *Id.* at 28:1-3.

Despite the Court's clear instructions, Plaintiffs have circulated draft DFSs directed toward the API and finished dose manufacturing Defendants that, with only one exception, are *entirely* duplicative of the finalized document requests.[16] *See* Exhibit O (comparing Plaintiffs' proposed DFSs to the document requests). In fact, Plaintiffs completely disregarded the Court's instruction to pare down the October draft, instead expanding the October draft to include even more requests, all of which are also covered by the document requests. During a meet and confer on Monday, January 27, Plaintiffs' conceded as much, agreeing that, with one exception, the DFS requested the same information as the Rule 34 document requests but on a Plaintiff-specific basis. For example, where the document requests seek production of certain test results for *all* batches of valsartan, the DFSs seek those same test results for the batches of valsartan dispensed to a particular Plaintiff.[17] Similarly, where the document requests seek production of *all*

[16] Consistent with the Court's instructions, Plaintiffs circulated distinct DFSs directed toward the different levels of the supply chain, including one DFS directed toward the API manufacturers and one DFS directed toward the finished dose manufacturers.

[17] As previously explained to Plaintiffs and the Court, the Manufacturer Defendants have no way of determining the particular batch or lot of valsartan that a particular Plaintiff received. They are unable to provide this type of Plaintiff-specific information without first knowing the particular batch and lot consumed by that Plaintiff. It is the Manufacturers' current understanding that Plaintiffs will be unable to provide them with specific batch and lot information.

communications with consumers, the DFSs seek communications with an individual consumer, the Plaintiff. The only non-duplicative DFS question that Plaintiffs could identify during this morning's meet and confer is the request that Defendants identify any theories of alternative causation, which is premature and will be the subject of extensive expert discovery. A chart demonstrating the overlap between the DFS requests and the corresponding document requests is attached as Exhibit O.

In other words, Plaintiffs seek to impose on the Manufacturer Defendants the burden of producing *all* valsartan related records, while also shifting to them the burden of reviewing these productions for documents relevant to each individual Plaintiff. Plaintiffs have gone so far as deleting language from the preamble to the draft DFSs stating that Defendants can answer the DFS questions by citing to already produced documents by Bates number, a type of response the Court explicitly endorsed in evaluating whether Defendants' lists of testing information were sufficient. *See* Ex. A, 1/15/20 Tr. at 48:5-16. But as this Court has repeatedly stated, Plaintiffs must have "skin in the game" and must do the work necessary to prove their cases. *See* 7/24/19 Tr. at 8:18-21 (stating that one of the "themes run[ing] through the case" is that "Plaintiffs have skin in the game"); 7/10/19 Tr. at 22:9-19 (stating that "plaintiffs have skin in this game" and "have to do their homework").

By Court order, Defendants must produce sales information by April 1, 2020. *See* Dkt. 318, ¶ 6. At that juncture, Plaintiffs will have at their fingertips the same data regarding distribution of valsartan as the Manufacturers have. There is simply no reason to shift the burden on Defendants to not only produce, but also to explain to Plaintiffs' counsel and their experts how this information may pertain to any particular Plaintiff. And putting aside the fact that it is *Plaintiffs'* burden to

prove that they consumed valsartan containing nitrosamines manufactured by a particular Defendant, there is no need for the Defendants to undergo this burdensome and time consuming process for each of the 2,000 valsartan personal injury actions that Plaintiffs anticipate filing.

Because the draft DFSs directed toward the API and finished dose Manufacturer Defendants are completely duplicative of the comprehensive discovery already ordered through the Rule 34 document requests, the Manufacturer Defendants respectfully request that the Court deny the Plaintiffs' current request for a DFS directed toward their two levels of the supply chain in its entirety. Plaintiffs have failed to identify any information that is not already covered by Rule 34 discovery—which is unsurprising, given the breadth of the document requests served on the Manufacturer Defendants.

6. Show Cause Process for Delinquent Plaintiffs

On January 14, 2020, Defendants filed a list of Plaintiffs who had (1) failed to serve their Short Form Complaints ("SFCs") through MDL Centrality; (2) served their SFCs through MDL Centrality, but in a way that did not allow the platform's data reporting tools to be used; or (3) entirely failed to file a SFC by the applicable deadline in Case Management Order No. 13 (Dkt. 187) (requiring all then-currently filed personal injury cases to file a SFC within 30 days). *See* Dkt. 338-4, Exhibit D (providing list of delinquent Plaintiffs). On January 16, 2020, the Court ordered that those Plaintiffs properly file and serve their SFCs. *See* Dkt. 342 at 1-2. As of the date of this filing, the Plaintiffs listed on attached Exhibit P have not complied with the Court's order. Accordingly, Defendants request that the Court issue Orders to Show Cause directed toward these Plaintiffs. *See* Jan. 16 Order, Dkt. 342 at 1-2.

Similarly, Defendants identified 20 Plaintiffs who failed to file a Plaintiffs' Fact Sheet ("PFS") by the January 15, 2020 deadline set by the Court. Accordingly, on January 24, 2020, Defendants served Overdue Plaintiff Fact Sheet Notices on counsel for these Plaintiffs, requesting that a PFS be filed within 7 days or the case will be placed on the next show cause agenda. The current CMOs relating to the show cause process specifically contemplate the parties negotiating over the "substantial completeness" of a filed PFS. Where, as here, the individual Plaintiffs are completely delinquent, rather than arguably deficient, in meeting their obligations, Defendants believe an expedited show cause process is warranted and seek the Court's guidance on whether entry of a separate order as to this process is needed.

7. Defendants' Leadership Structure

There are currently four members of Defendants' Executive Committee. Following a recent telephonic meet and confer on global MDL management issues, Plaintiffs expressed frustration with the fact that 20 attorneys dialed in to the teleconference.[18] Defendants do not believe that a change in leadership structure will affect the number of attorneys who have an interest in listening to a particular meet and confer that affects their clients, especially given that there are now approximately 50 Defendants in this MDL. Nevertheless, Defendants are in the process of potentially adding D'Lesli M. Davis, counsel for McKesson Corp., to the Defendants' Executive Committee a representative of the Wholesaler level of the supply chain, subject to negotiation of a cost-sharing agreement between the Defendants.

[18] At least seven participants were Plaintiffs' counsel from six different firms, while *only two counsel spoke on behalf of Defendants*, but multiple attorneys from the law firms represented on the DEC opened teleconference lines to listen to the call and take notes.

8. Challenges to Confidentiality Designations

The agreed Discovery Confidentiality Order (Dkt. 139) ("DCO") entered in this MDL governs challenges to confidentiality designations. Specifically, the DCO provides that a receiving party who objects to the designation of "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" shall "serve on the Producing Party . . . a written objection to such designation which shall describe with particularity the documents or information in question and shall state the grounds for objection." DCO at ¶ 20(a). Counsel for the Producing Party then shall respond in writing within 21 days of receiving the written objection, stating with particularity the grounds for asserting that the information is confidential. *Id*. The DCO further provides that counsel shall confer in good faith within fourteen days of the date of the Producing Party's response to resolve the dispute. *Id*. Under the DCO, *only after the parties have determined that a dispute as to a confidentiality designation cannot be resolved by agreement can the dispute be raised to the Court*. *Id.* ¶ 20(b).

Rather than utilizing the process ordered by this Court and *agreed to by Parties*, Plaintiffs instead submitted a letter to the Court after 5:30 pm Eastern on Friday, January 24. Given that Plaintiffs have not abided by the DCO, and that Defendants have been given less than one business day to respond to Plaintiffs' letter in this submission, Defendants request that these confidentiality designations not be considered at the January 28 Case Management Conference, and that the Parties be given the opportunity to meet and confer on the confidentiality designations addressed in Plaintiffs' January 24 letter, in accordance with the procedure set forth in the DCO.

9. Product Preservation

On the evening of Thursday, January 23, Plaintiffs served emails on the Core Discovery Defendants inquiring as to the disposition of recalled valsartan product. Defendants continue to work informally with Plaintiffs to share information about the status of recalled valsartan product, as directed by the Court during the January 15 telephonic Case Management Conference.

10. Core Discovery

The Core Discovery Defendants continue to supplement their productions as new communications with the FDA become available. However, Defendants request that the 7-day deadline for supplemental productions be extended to 14 days to provide counsel sufficient time to collect and review ongoing communications.

(a) ZHP and Related Defendants

ZHP supplemented its Core Discovery production on January 22. Additionally, Prinston has identified new Core Discovery documents created on January 23, and will be producing those documents prior to the January 28 hearing.[19]

[19] On January 22, Solco produced a number of documents that it identified in the course of collecting facts relating to its recall of valsartan and the disposition of recalled product. These documents were not previously produced in Core Discovery because Solco is not subject to the Core Discovery Order. The Court has recognized that distributors like Solco, who distributes ZHP's finished dose valsartan, have the same discovery obligations as other distributors, such as McKesson or Cardinal. *See* 11/20/19 Tr. at 110-111 ("MS. HILTON: Correct. But distributors, as to, like a McKesson or a Cardinal, is, to us, to plaintiffs, is a different type of distributor than a vertically integrated U.S. arm that sells drugs to McKesson and Cardinal. THE COURT: Let's put them in the same category."). However, in the interest of sharing information on the issue of product disposition, Solco has produced information to counsel and will continue to work to share information pertinent to these issues. Solco is currently working to obtain additional information about that status of product currently held by third parties assisting with its handling of recalled product.

(b) The Teva Defendants

The Teva Defendants served a supplemental Core Discovery production consisting of FDA correspondence on December 27, 2019. In response to a request from Plaintiffs' counsel, the Teva Defendants served a production consisting of one additional document identified following review of said FDA correspondence on January 22, 2020, and confirmed that no additional correspondence had taken place since December 18, 2019.

(c) Hetero USA

Hetero USA supplemented its Core Discovery production on January 6th. Unredacted copies of core discovery documents were re-produced per the Court's order on January 23rd. Hetero USA is producing additional core discovery documents prior to the January 28th conference.

(d) Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC

Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC supplemented their Core Discovery production on January 22. In addition, unredacted copies of Core Discovery documents were re-produced on January 22 per the Court's Order dated December 11, 2019 (Dkt. 319).

(e) Mylan

Pursuant to the Court's Order, Mylan supplemented its production with unredacted copies of the core discovery documents on January 22, 2020. Moreover, since the January 15, 2020 telephonic status conference, Mylan also supplemented its production of FDA recall correspondence to include communications as recent as January 16, 2020.

(f) Torrent

Torrent is continuing to work to identify new Core Discovery Documents and will produce those documents prior to January 31.

11. ESI Update

Upon the finalization of ESI custodians and preliminary search terms, Mylan has begun the process of custodial collections and analysis, including the performance of custodial email hit counts. This process has revealed the potential overbreadth of the search terms. Mylan's counsel has raised its concerns with Plaintiffs' counsel, and looks forward to continuing those discussions to ensure the scope of ESI is reasonable and proportionate.

Counsel for the ZHP Defendants and counsel for the Plaintiffs have exchanged proposed translations of search terms. Counsel are in the process of discussing these terms and will raise areas of concern (if any) with the Court tomorrow.

In general, the Manufacturer Defendants are continuing to collect and search their data and will discuss any problematic search terms with Plaintiffs as soon as possible.

12. Status of Service on Hetero Drugs, Ltd., Hetero Labs, Ltd., and Aurobindo Pharma, Ltd.

Hetero USA has advised its parent corporations, Hetero Drugs and Hetero Labs, that Plaintiffs have reported service of process upon Hetero Drugs and that the Indian entities should retain counsel to enter appearances on their behalves. Counsel for Hetero USA has not been retained as counsel for either Hetero Labs or Hetero Drugs. To-date, Hetero USA has not been informed that Hetero Labs or Hetero Drugs has retained counsel, although it is Hetero USA's understanding that they are in the process of doing so.

Counsel for Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC are not aware of any service of process on Aurobindo Pharma Ltd. in this litigation.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
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